UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION	**Case No. 2:23-MD-03080** **MDL No. 3080** **Hon. Brian R. Martinotti** **Hon. Rukhsanah L. Singh**

DOCUMENT RELATES TO:

The State of Mississippi, ex rel. Lynn Fitch, Attorney General v. Eli Lilly & Co., et al.
No. 2:23-cv-04364 (BRM)(RLS)

MISSISSIPPI'S OPPOSITION TO MANUFACTURER DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

INTRODUCTION

The Manufacturer Defendants have known since day one that GLP-1 drugs are at-issue in this case. The GLP-1s were included in the State's original, June 2021 complaint and in both subsequent amendments. In fact, each Manufacturer Defendant admitted in their November 2022 Answers that GLP-1s are at-issue and included in the State's claims. Further, all Defendants have participated in discovery related to all at-issue drugs. Manufacturer Defendants alone have produced nearly 280,000 documents to the State related to the at-issue GLP-1s. The Manufacturers cannot credibly claim they are surprised that the State intends to pursue its claims as they relate to the GLP-1s.

Tellingly absent from the lengthy record in this case, until just recently, is any allegation or argument by the Manufacturer Defendants that the GLP-1s are covered by patents or that patent law preempts the State's claims. The State's complaint does not mention GLP-1 patents, allege misuse of patents, or tie Defendants' misconduct to patents in any way. Indeed, the State's allegations regarding Defendants' misconduct are the same for all at-issue drugs – those that are purportedly patent-protected and those that are not.

Notably, in their Answers, the Manufacturers did not assert patent law as a defense to the State's claims. (Miss. Dkts. 116, 117, 118). Nor did they argue patent preemption in Rule 12(b)(6) motions filed over the last four years in this case or in at least seven other factually similar cases also involving GLP-1s. (Miss. Dkts. 84, 104; *see,*

e.g., City of Miami v. Eli Lilly & Co., et al., 2022 WL 198028, at *1, n.1 (S.D. Fla. Jan. 21, 2022); *Harris Cnty., Texas v. Eli Lilly & Co., et al.*, 2020 WL 5803483, at *1 (S.D. Tex. Sept. 29, 2020)).

In their Rule 12(b)(6) motion filed in this case on March 21, 2022, the Manufacturers argued that the State's allegations against them are insufficient to state violations of the Mississippi Consumer Protection Act (MCPA) and the common law. The Mississippi Federal Court denied the Manufacturers' motion in its entirety and held that the State's claims are pled with "in-depth detail" – pleading that satisfies the heightened Rule 9(b) standard even though not required to state an MCPA claim. (Miss. Dkt. 111 at 14 ("In its 118-page Complaint, the State delineates each Manufacturer Defendant's alleged participation in the "Insulin Pricing Scheme," including specific drugs, prices, timelines, knowledge, and intent.")). The court similarly denied the PBM Defendants' separate Rule 12(b)(6) motion. (Miss. Dkt 144 at 8).

Importantly, the Manufacturers' Rule 12(b)(6) motion was not limited to any subset of the at-issue drugs. Their arguments were directed at all at-issue drugs, referring to "diabetes medications" nearly 30 times in their motion. (*See, e.g.,* Miss. Dkt. 84 at 5 (arguing that the complaint "alleges that the Manufacturer and PBM Defendants engaged in a purported "Insulin Pricing Scheme" that increased the prices the State and its citizens paid for the *diabetes medications*") (emphasis added)). Thus, the Mississippi Court's rejection of those arguments and its ruling on the sufficiency of the State's allegations applies to all at-issue drugs.

Nearly two years after serving their Answers, the Manufacturers have filed a motion to dismiss pursuant to Rule 12(c) raising what they call a "threshold question" that should be "promptly" decided. (MDL Dkt. 131 at 3). Focusing on the GLP-1s, the Manufacturers make two arguments: (1) that the State's allegations related to GLP-1s are insufficient; and (2) that the GLP-1s are covered by patents which preempt the State's claims related to those drugs.

The first argument has already been decided. The State's allegations have been found sufficient to state each of its claims against the Manufacturers, and they have not provided any factual or legal basis for this Court to reconsider the Mississippi Court's ruling. Further, the State's claims are premised on unfair and deceptive conduct that is the same for all at-issue drugs. That some of the at-issue GLP-1s are newer is immaterial and certainly does not preclude Defendants from using the GLP-1s to further their scheme.

The Manufacturers' second argument – patent preemption – is factually and legally unsupported. For starters, the Manufacturers have not met their heavy Rule 12(c) burden of proof – they have not cited undisputed facts or otherwise provided proof that the GLP-1s are covered by patents or, even if so, that the Manufacturers have the right to assert those patents as a shield to liability.

Lack of proof aside, patent law does not immunize unlawful conduct such as that alleged here. Courts around the country, including the Federal Circuit and the United States Supreme Court, agree that patent law *does not preempt* state law claims based

on "marketplace misconduct" - unlawful conduct that is not regulated by federal patent laws.

Tellingly, the Manufacturers largely ignore this well-developed body of law and instead rely on two facially distinguishable cases. Both involve state laws or claims exclusively targeting patented drugs with no allegations of unlawful conduct. The State's claims here are much broader and are premised on Defendants' unfair, deceptive, and conspiratorial conduct, which is wholly separate and unrelated to patent law. Such conduct has been recognized as unlawful by every court to consider it, including the Mississippi Court in this case. (Miss. Dkt. 111, 144).

The Manufacturers' Rule 12(c) motion is factually and legally flawed and should be denied.

LEGAL STANDARD

Rule 12(c) motions are disfavored as contrary to "the long-established policy of the federal rules [] to decide cases on the proofs." *Blanchard Sec. Co. v. Rahway Valley R.R. Co.*, 2004 WL 7329960, at *3 (D.N.J. Dec. 27, 2004). A Rule 12(c) motion must be denied unless the movants establish that no material issue of fact remains to be resolved. *See Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008).

Courts typically apply the same standard to Rule 12(c) motions as those under Rule 12(b)(6). *In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 380 (D.N.J. 2018) (citation omitted). "Under either rule, the Court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the

nonmoving party." *Id.* (citation omitted). A "complaint should not be dismissed unless it appears beyond doubt that the facts alleged in the complaint, even if true, fail to support the claim." *Id.* (internal quotation marks and citation omitted). The moving party bears the burden to prove that there are no material issues of fact to be resolved and that the movant is entitled to judgement as a matter of law. *Mu Sigma, Inc. v. Affine, Inc.*, 2018 WL 1064211, at *4 (D.N.J. Feb. 27, 2018) (Martinotti, J.).

ARGUMENT

I. The State's Claims Are Sufficiently Pled.

A. The State's Claims were Challenged and Found to be Sufficient

The Manufacturers argue that the State's allegations as to the GLP-1s are insufficient. (MDL Dkt. 200-1 at 13-15). However, the Manufacturers have already challenged the sufficiency of the State's allegations as to all at-issue drugs and their motion was denied in its entirety. The Manufacturers did not seek reconsideration of that ruling and have not identified any new facts or law justifying reconsideration now, more than two years later, by a different court.

Any argument that the Mississippi Court's ruling somehow does not apply to the State's GLP-1 allegations should be rejected out of hand. The Manufacturers' 12(b)(6) motion was expressly directed at all at-issue drugs, as was the court's ruling denying that motion. (*See, e.g.,*, Miss. Dkt. 111 at 1, 2 (order recognizing that the State's allegations pertain to diabetes medications beyond just insulin); Miss. Dkt. 84 (Manufacturers

12(b)(6) memorandum, referring to "diabetes medications" nearly 30 times)). The Manufacturers have not claimed otherwise.

Because the State's allegations have been found to be sufficient and because the Manufacturers failed to identify any factual or legal basis for reconsidering the Mississippi Court's ruling, their Rule 12(c) motion based on the sufficiency of the State's pleadings should be denied.

B. The State's Allegations Are More Than Sufficient to Defeat the Manufacturer's Motion

The Manufacturers' contention that the State has not pled any unlawful conduct related to the GLP-1s is also wrong. First, to make their argument, the Manufacturers mischaracterize the State's allegations. Contrary to the Manufacturers' assertions[1] and viewing the allegations and drawing all reasonable inferences in favor of the State, the complaint alleges the following relevant facts:

- Insulins and GLP-1s are used to treat Type 2 diabetics which represent 90-95% of all diabetics. (TAC ¶¶ 239, 274-76).[2]

[1] Manufacturers claim that the complaint "devotes a mere four paragraphs and one figure to GLP-1s." (MDL Dkt. 200-1 at 5). In the next sentence, however, they purport to summarize the "entirety of the facts pled as to GLP-1s" and cite to *nine* paragraphs in the complaint. (*Id.*). As demonstrated herein, these statements and characterizations are false.

[2] Citations to "TAC" refer to the Third Amended Complaint, Miss. Dkt. 71.

- Manufacturer Defendants dominate the market for all diabetes medications, including insulins and GLP-1s. (TAC ¶¶ 5, 277, 365, 472, 523).
- Insulins and GLP-1s cost the Manufacturers very little to produce. (TAC ¶¶ 13, 272, 350, 440-41, 523).[3]
- GLP-1s, like insulins, are treated as interchangeable commodities by the Manufacturers and PBMs, and are negotiated and horse-traded with insulins for formulary placement and Manufacturer Payments. (TAC ¶¶ 275, 349, 545; *id.* at Fig. 10; Senate Rpt. at 62, 79).
- Insulins and GLP-1s are included together in the same rebate contracts – defined as the same class of drugs (diabetes) – between Manufacturers and PBMs. (TAC ¶¶ 131, 188, 231, 457, 545; Senate Rpt. at 79).[4]

[3] A recent study, published after this action was filed, corroborates the State's allegations and concludes that Ozempic could be profitably manufactured for less than $5 per month, despite having a list price of nearly $1,000. *See https://fortune.com/europe/2024/03/28/ozempic-maker-novo-nordisk-facing-pressure-as-study-finds-1000-appetite-suppressant-can-be-made-for-just-5/*.

[4] Citations to "Senate Rpt." refer to the Senate Finance Committee's January 2021 report "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," *available at* https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf. As the Manufacturers note, the report was incorporated by reference in the TAC, and may therefore be considered by the Court. (MDL Dkt. 200-1 at 5).

- The Manufacturers make the same Manufacturer Payments to PBMs for insulins and GLP-1s, including rebates, administrative fees, price protection fees, etc., and do so in exchange for preferential formulary placement of those drugs. (TAC ¶¶ 20-23, 315, 317, 350, 386, 390, 397-400, 545).
- The Manufacturers have made the same lockstep, artificial, and extreme price increases, over the same period of time, for the GLP-1s as with insulin. (TAC ¶¶ 287, 289-95, 350, 523, 540; *id.* at Figs. 7-10; Senate Rep. at 65).
- The same internal Manufacturer pricing committees set the prices and Manufacturer Payments for both insulins and GLP-1s. (*See, e.g.,* Senate Rep. at 52, n. 255 ("Pricing decisions for drugs marketed and sold by Novo Nordisk in the U.S. are made by its USPC.")).
- The same Pharmacy & Therapeutics committees within the PBMs evaluate both insulins and GLP-1s, which are included on the same PBM formularies at the center of the scheme. (TAC ¶¶ 457-60, 473, 522; Senate Rep. at 35-36).
- The Manufacturers report the list prices of insulins and GLP-1s in the same manner, to the same entities, knowing that their reported prices are

untethered from their actual prices and are used to set the prices paid by diabetics and the State. (TAC ¶¶ 50, 65, 79, 302, 435-40, 475, 522).

- The Manufacturers failed to disclose and concealed their actual prices for insulins and GLP-1s. (TAC ¶¶ 432-443, 463-65, 467-68, 471, 475, 479, 509, 522).
- In furtherance of the scheme, the PBMs ensure that the Manufacturers' reported prices are used to set the amount that payors, such as the State, and diabetics pay for insulins and GLP-1s. (TAC ¶¶ 179, 226, 229, 362, 417, 426, 429, 444-45, 449, 473, 522).
- Defendants' misconduct with respect to both insulins and GLP-1s has significantly harmed diabetics by depriving diabetics access to lower priced drugs and affordable treatments. (TAC ¶¶ 26-29, 362, 462, 483-97, 527)[5]).

Clearly, the State's overall allegations regarding the treatment of the at-issue drugs in the marketplace very much apply to the GLP-1s.

The differences Manufacturers identify between insulins and GLP-1s are insignificant. *First*, Manufacturers assert that the State's factual allegations about the scheme somehow do not apply to GLP-1s because they are new drugs. (MDL Dkt. 200-1 at 14). This Court has previously considered the same argument in the consumer class

[5] Recent reports, released after this case was filed, further corroborate the State's allegations related to GLP-1s. *See*, *e.g.,* https://www.cbsnews.com/news/ozempic-diabetes-drugs-high-price-effects/

action and found it "unconvincing." *In re Insulin Pricing Litig.*, 2020 WL 831552, at *4, (D.N.J. Feb. 20, 2020) (Martinotti, J.). As the Court observed in that case, "the length of time the New Insulins have been on the market bears no relationship to whether their prices are the result of the same price-fixing scheme Plaintiffs allege regarding the other insulins." *Id.*[6]

Second, Manufacturers suggest that research and development ("R&D") costs make up a "large percentage" of the GLP-1s' prices thereby distinguishing them from insulins. (MDL Dkt. 200-1 at 5, 14-15). However, their cited sources, (*id.* at 5, n.4), actually refute this. The Senate report indicates that the Manufacturers' R&D costs constituted an *insignificant* portion of their diabetes franchise spending, even with GLP-1s included. While Eli Lilly reported plans to invest most of its R&D spending on three drugs including its GLP-1 Trulicity, the Senate committee noted that "even with these significant studies, the company's R&D spending *for its entire diabetes franchise* was budgeted to be just one-third of its sales, goods and administrative expenses[.]" (Senate Rep. at 21). Similarly, according to the Senate committee's figures, Sanofi's total five-year R&D cost for its GLP-1 product Soliqua *and four other drugs*, was approximately 2.4% of the company's net sales ($902 million in R&D, and net sales of about $37 billion). (*Id.* at 22-23). Novo Nordisk "failed to provide a detailed accounting of its

[6] Further, the GLP-1s are in fact older than some of the at-issue insulins – for example, Victoza and Trulicity (GLP-1s) were FDA-approved in 2010 and 2014, before Toujeo, Tresiba, and Basaglar (insulins). (TAC ¶ 277 Tbl. 1).

R&D expenditures" but the Senate report noted its total R&D expenditures for diabetes and obesity from 2017 to 2019 were approximately $5.2 million, and places its R&D spending far below Sanofi's. (*Id.* at 23). Further, To the extent the Manufacturers assert these R&D expenses are significant, it is a disputed issue of fact that cannot be resolved on a Rule 12(c) motion. *Rosenau*, 539 F.3d at 221.[7]

Neither of the purported differences pointed to by the Manufacturers to distinguish GLP-1s from the other at-issue drugs are material to the Court's analysis.

Additionally, the Manufacturers recently attempted to exclude GLP-1s from discovery in this MDL based on many of the same arguments that they assert in their Rule 12(c) motion. (MDL Dkt. 166 at 18-20). The Court, however, rejected their position and entered a discovery plan expressly providing that "the relevant drugs for discovery include insulin products and glucagon-like peptide receptor agonists ("GLP-1s")." (MDL Dkt. 198 at § II(D)). As alleged by the State and recognized by the Mississippi Court, the unlawful scheme executed by Defendants applies equally to all at-issue drugs including the GLP-1s.

[7] Notably, the Manufacturers cite paragraph 270 of the State's complaint for the general proposition that R&D costs may comprise a large part of a drug's price. The State does not allege that R&D costs for GLP-1s fall into this category, and in fact, alleges the opposite. (TAC ¶¶ 13, 272, 350, 440-41, 523). Further, in their Answers, Defendants Novo Nordisk and Sanofi denied the State's allegations in paragraph 270. (Miss. Dkt. 116 at ¶ 270; Miss. Dkt. 118 at ¶ 270).

II. The Manufacturers Have Failed To Meet Their Burden of Proof As To Patent Preemption.

Manufacturer Defendants, as the moving parties, have the burden to establish that there are no disputed issues of material fact. *See In re Asbestos Prod. Liab. Litig.*, 822 F.3d 125, 133 n.6 (3d Cir. 2016) ("federal preemption is an affirmative defense on which the defendant bears the burden."); *In re Allergan Biocell Textured Breast Implant Products Liab. Litig.,* 537 F. Supp. 3d 679, 705 (D.N.J. 2021) (Martinotti, J.). Their motion falls well short and should be denied.

As a threshold matter, the Manufacturers have presented no facts, undisputed or otherwise, demonstrating that the at-issue GLP-1s are patent-protected, or that the Manufacturer Defendants own any relevant patents or patent rights – foundational elements of the Manufacturers' affirmative defense of patent preemption. *See Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 196 F.3d 1366, 1370 (Fed. Cir. 1999) (patent preemption is an affirmative defense).

The Manufacturers' preemption argument is not based on allegations in the complaint or admissions in their Answers. Rather, the Manufacturers baldly claim that the GLP-1s "were covered by patents at the time the State filed the lawsuit and remain under patent . . . ." (MDL Dkt. 200-1 at 6). In a footnote, the Manufacturers reference several patent numbers and then cite a district court case for the notion that courts may take judicial notice of "patent documents" when considering a motion to dismiss, (*id.* at 6, n. 5.), but they did not attach any patent documents to their motion. Nor did the

Manufacturers explain how the footnoted patent numbers "cover" or even relate to the GLP-1s, when they were issued or expire, or even claim to own or have rights to the footnoted patent. Instead, the Manufacturers assume that the Court and the State will blindly accept the statements in their brief or else that the burden has somehow shifted to the State to disprove their affirmative defense. Neither is sufficient to satisfy their heavy burden.[8] Accordingly, their motion should be denied. *Mu Sigma, Inc.*, 2018 WL 1064211, at *4.

III. Patent Preemption Fails.

There are three types of preemption: (1) explicit preemption, (2) field preemption, and (3) conflict preemption. *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1332 (Fed. Cir. 1998) (citation omitted). The Manufacturers do not specify what type of preemption they assert, but conflict preemption is the only possibility.[9] Conflict preemption includes two sub-types. The first, impossibility preemption, is

[8] Even if the Manufacturers satisfied this threshold issue, which they have not, the State's claims would still not be preempted.

[9] There is no explicit preemption or field preemption. *See Hunter Douglas*, 153 F.3d at 1332 ("federal patent law plainly does not provide for explicit preemption"); *id.* at 1333 ("Because of the lack of such congressional intent, in conjunction with the underlying presumption disfavoring preemption, there is no field preemption of state unfair competition claims" even when such claims "rely on a substantial question of federal patent law.").

facially inapplicable.[10] The second is when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress[.]" *Id.* (citation and internal quotations omitted). This second sub-type of conflict preemption arises in the two cases relied upon by the Manufacturers and is the only potential basis for their motion. It too fails.

To shoehorn the State's claims into conflict preemption, the Manufacturers characterize the claims as merely based on pricing decisions alone, unrelated to any allegations of unlawful conduct. This is false, as the Complaint allegations make clear. Notably, the Manufacturers similarly mischaracterized the State's claims in their original Rule 12(b)(6) motion, arguing that State's allegations are insufficient because the MCPA "prohibits only *deceptive* prices – not allegedly high prices." (Miss. Dkt. 84 at 1 (emphasis in the original); *id.* at 1 (asserting that "all the State alleges" is "that the "price" of diabetes medications is higher than it should be, and that the PBMs and Manufacturers in turn make more money") (citations omitted)). The Mississippi Court rejected Manufacturers' overly simplistic view, found that the State "plausibly alleges [a] deceptive practice under the MCPA," and denied the Manufacturers' motion in its entirety. (Miss. Dkt. 111 at 13, 17 (citations omitted)). Indeed, the State alleges that the Manufacturers published false list prices that they knew were untethered to the actual

[10] Impossibility preemption applies when "it is impossible for a private party to comply with both state and federal requirements." *Hunter Douglas*, 153 F.3d at 1332 (citation omitted).

prices and that they knew were used to set the prices paid by Mississippi diabetics and payors, including the State. They repeatedly and in lockstep raised the list prices of all at-issue drugs, misrepresented and concealed the reasons behind the price increases, and continually increased the amount of Manufacturer Payments to the PBMs with the intent and effect of foreclosing diabetics' access to lower priced treatments. They then worked with PBMs to conceal and obfuscate their misconduct in furtherance of their scheme, in order to maximize Defendants' profits, to the detriment of diabetics and the State.

Accordingly, the State's claims are based on conduct that is unlawful under the MCPA, which applies to all at-issue products - insulins and GLP-1s, whether patented or unpatented. The unlawful conduct resulted in false, inflated, and deceptive prices for all at-issue drugs, but it is the misconduct, not simply the setting of prices, that forms the basis of liability. As set forth below, case law resoundingly and conclusively establishes that federal patent law does not preempt state law claims based on unlawful conduct that is not regulated by patent law.

A. The Presumptions Set Forth By the U.S. Supreme Court Weigh Heavily Against Preemption of the State's Claims

"The Supreme Court has set forth two presumptions that guide the preemption analysis." *Hunter Douglas*, 153 F.3d at 1331-32.

> *First*, it is presumed that Congress does not "cavalierly" preempt state law causes of action, for "the States are independent sovereigns in our federal system." "[T]he historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest

> purpose of Congress," particularly when Congress has "legislated ... in a field which the States have traditionally occupied." *Second*, preemption analysis is guided by the "oft-repeated" principle that "[t]he purpose of Congress is the ultimate touchstone."

Id. at 1332 (emphases added) (citations omitted).

1. Consumer Protection Is an Area Traditionally Regulated By States

There is a "presumption against finding pre-emption of state law in areas traditionally regulated by the States." *California v. ARC Am. Corp.*, 490 U.S. 93, 101 (1989). "Given the long history of state common-law and statutory remedies against … unfair business practices, it is plain that this is an area traditionally regulated by the States." *Id.*[11] Likewise, "[t]hroughout our history the several States have exercised their police powers to protect the health and safety of their citizens… which are primarily, and historically, . . . matter[s] of local concern[.]" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (internal quotation marks and citation omitted). Under the Supreme Court's jurisprudence, "the presumption against preemption has greater force because of the

[11] The Supreme Court's analysis in *ARC Am.* highlights the high bar for finding a conflict sufficient to overcome the presumption against preemption. The Supreme Court held that federal antitrust law prohibiting recovery by indirect purchasers did not preempt state antitrust laws, which allowed recovery by indirect purchasers. 490 U.S. at 101. Despite the apparent conflict between the federal and state rules, the Supreme Court found that the state laws "are consistent with the broad purposes of the federal antitrust laws: deterring anticompetitive conduct and ensuring the compensation of victims of that conduct." *Id.* at 102. The Court stated that it would be "inappropriate" to consider the federal rule "as defining what federal law allows States to do under their own antitrust law." *Id.*

states' long-standing governance over such affairs." *Hunter Douglas*, 153 F.3d at 1334 (citations omitted).

Here, Congress has not evidenced *any* intent, much less a "clear and manifest purpose" for federal patent law to preempt state tort law. "[T]he law of unfair competition… [has] coexisted harmoniously with federal patent protection for almost 200 years, and Congress has given no indication that their operation is inconsistent with the operation of the federal patent laws." *Id.* (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166 (1989)) (quotation marks omitted). The patent statute does not even expressly prohibit states from regulating the price of patented goods, *Biotechnology Indus. Org. v. D.C.* , 496 F.3d 1362, 1372 (Fed. Cir. 2007), and there certainly is no clear and manifest intent of Congress to prohibit states from regulating unfair and deceptive conduct related to patented products. Thus, the first presumption weighs against preemption – with added force since the state law at issue governs areas traditionally regulated by the states.

2. Congress did not intend for patent law to immunize unlawful conduct in the marketplace.

The Supreme Court has identified three objectives of the federal patent laws:

> *First*, patent law seeks to foster and reward invention; *second* it promotes disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires; *third*, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.

Hunter Douglas, 153 F.3d at 1333 (quoting *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979)) (emphases added).

The Manufacturers focus on the first objective and contend that patent law immunizes their misconduct and preempts the State's GLP-1 claims simply because the allegations relate to the price of a patented good. The Manufacturers are wrong. The Federal Circuit stated that Congress designed patent law to reward invention in a specific way:

> Patents are designed to promote innovation *by providing the right to exclude others from making, using, or selling an invention*. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

Biotech, 496 F.3d at 1373 (quoting H.R. Rep. No. 98-857, at 17 (1984)) (emphasis added). Patents reward inventors with the right to exclude other sellers of the patented product for a time. While the patent monopoly may allow greater profits in some circumstances it *does not* liberate the inventor from other competition. After all, a patented $500 mousetrap is unlikely to generate any profits, because competitor products could remain on the market at a much lower price. Moreover, the patent monopoly does not excuse the patentee from the rules of the marketplace. As the *Loestrin* court explained, "A patent conveys a temporary monopoly on individual drugs – not a right to use… patents as part of a scheme to interfere with competition beyond the limits of the patent monopoly." *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 352 (D.R.I. 2017).

The court in *In re EpiPen Marketing, Sales Practices and Antitrust Litig.* evaluated the same argument Manufacturers make here, with defendants asserting "that public policy supports Mylan's freedom to set prices for the EpiPen – as its patent holder – because the exclusivity granted by patent rights encourages innovation." 336 F. Supp. 3d 1256, 1338, n.25 (D. Kan. 2018). The *EpiPen* court found that, as alleged by plaintiffs, the defendants "did more than simply set prices as a patent holder" but instead "engaged in various anticompetitive and fraudulent competition[.]" *Id.* Accepting the plaintiff's allegations as true, the court concluded that "public policy does not favor this type of conduct." *Id.*

There are numerous GLP-1s. Each Manufacturer sells at least one allegedly patented GLP-1. Thus, no Manufacturer has a patent monopoly over the GLP-1 drug category. Any lawful patent monopoly enjoyed by a particular GLP-1 could not and did not drive GLP-1 prices. Indeed, the purported GLP-1 patents are irrelevant to competition within the GLP-1 category. ***Most importantly, competition among the GLP-1s should have kept prices low, but did not. The State alleges the Manufacturers manipulated the GLP-1 market by paying PBMs for favorable or exclusive formulary placement and disadvantaging or excluding lower-priced, competitor drugs – just as they did for the unpatented at-issue drugs.*** Defendants' unlawful conduct applicable to *all* of the at-issue drugs, patented or not, artificially inflated the prices of GLP-1s.

Congress' purpose does not support patent preemption of the State's claims that unlawful conduct caused artificially inflated prices wholly separate from patent exclusivity.

B. The States' Claims Are Based On Manufacturers' Misconduct and Are Not Preempted By Federal Patent Law.

The Manufacturers contend that patent preemption cases involving allegations of misconduct in the marketplace are somehow inapposite to the State's claims. (MDL Dkt. 200-1 at 12). Yet case law plentifully establishes that allegations of misconduct in the marketplace, like that alleged by the State, lead to no patent preemption, unlike the two cases Manufacturers cite. To avoid this outcome, Manufacturers assert that the State's claims are about high prices alone and that patent law shields them from any liability related to patented medications. (*See id.* at 8-12). This characterization of the allegations, however, is divorced from reality. First, as discussed above, the State's claims are precisely about unlawful conduct, with the false, inflated prices resulting from that unlawful conduct. Second, the marketplace has rules, which the State may enforce against all parties, patentee or not. Indeed, a robust body of case law establishes that state law claims based on marketplace misconduct, like Mississippi's, are not preempted by federal patent law.

Under well-established Federal Circuit precedent, if a plaintiff bases its action on conduct that is not protected or governed by federal patent law, the state law remedy is not preempted. *Hunter Douglas,* 153 F.3d at 1335. As the Federal Circuit has recognized,

"[a] state has every right to protect its citizens and residents" from wrongful conduct "by any party, including a patentee." *Dow Chemical Co. v. Exxon Corp.*, 139 F.3d 1470, 1477 (Fed. Cir. 1998). Claims arising from bad faith misconduct in the marketplace are not preempted by federal patent law. *In re Loestrin*, 261 F. Supp. 3d at 357 (citing *Dow*, 139 F.3d at 1478).

In *Dow*, the Federal Circuit considered whether a state unfair competition claim was preempted by federal patent law. 139 F.3d at 1471. The Federal Circuit noted that the tort's "required elements take place in the marketplace[.]" *Id.* at 1477. The court's majority judged this to be "the primary issue" ultimately leading it to conclude that the claim was not preempted, and to reverse the district court. *Id.*

In *Hunter Douglas*, the Federal Circuit considered "to what extent federal patent law preempts state law causes of action prohibiting tortious activities in the marketplace, when to prevail on them, the plaintiff must prove that a United States patent is either invalid or unenforceable." 153 F.3d at 1321. After thorough analysis of patent preemption, the Federal Circuit found that "to escape preemption, the plaintiff would need to allege and prove ultimately [bad faith in the marketplace]." *Id.* at 1337. Of course, unlike the causes of action in *Hunter Douglas*, the State's claims in this case do *not* require proof of any patent invalidity. The State's claims are based on misconduct wholly outside of the patent system and unrelated to any patent issue, making its case even more obviously outside the scope of patent preemption.

In *Zenith Elecs. Corp. v. Exzec, Inc.*, the Federal Circuit confirmed its decisions in *Dow* and *Hunter Douglas* and held that patent law did not preempt the state law claims involving allegations of bad faith marketplace misconduct. 182 F.3d 1340, 1355 (Fed. Cir. 1999). The Federal Circuit also explained the lack of conflict between patent law and unfair competition law: "patent law is not frustrated because bad faith marketplace [conduct] concerning patents do[es] not further the purposes of patent law." *Id.* at 1354. (citation omitted).

District courts across the nation have repeatedly and consistently cited and applied the holdings of *Dow* and *Hunter Douglas* to find that allegations of marketplace misconduct are not preempted by patent law. For example, the court in *In re Loestrin 24 Fe Antitrust Litig.* found it "plain" under the precedents that state law claims, including consumer protection claims, were not preempted because they required different elements than a claim under patent law, and the tort occurred in the marketplace. 261 F. Supp. 3d at 357. The court in *EpiPen*, quoting *Dow*, agreed, finding that the plaintiffs' state consumer protection claims were not preempted because they alleged misconduct in the marketplace. 336 F. Supp. at 1334. The *EpiPen* defendants cited the same two cases cited by Manufacturers here: *Biotech*, 496 F.3d at 1374, and *Se. Pa. Transp. Auth. v. Gilead Scis., Inc.* ("*SEPTA*"), 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015). *In re EpiPen*, 336 F. Supp. 3d at 1333. The *EpiPen* court considered the cases and found those cases unavailing, noting that "Defendants cited no authority holding that the federal patent law permits a patent holder to commit unfair and deceptive practices that violate state

consumer protection laws – simply because it owns patent rights. Indeed, many courts have concluded just the opposite." *Id.* at 1333-34. *See also In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 215-18 (S.D.N.Y. 2012); *Picone v. Shire PLC,* 2017 WL 4873506, at *14 (D. Mass. Oct. 20, 2017); *Studio 010 Inc. v. Digital Cashflow LLC*, 2022 WL 1215529, at *4 (W.D. Wash. Apr. 4, 2022).

This Court, in alignment with other district courts and the Federal Circuit, has also recognized that allegations of bad faith in the marketplace overcome patent preemption, including with regard to state consumer protection law. *In re Effexor Antitrust Litig.*, 357 F. Supp. 3d at 383; *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 409 (D.N.J. 2018). *See also In re K-Dur Antitrust Litig.*, 2007 WL 5297755, at *24-25 (D.N.J. Mar. 1, 2007) (recognizing that "evidence of marketplace conduct can revive a claim otherwise subject to preemption under federal patent law" and finding plaintiffs' claims preempted due to "the absence of any legally cognizable allegations of marketplace conduct").

Case law addressing "reverse payment settlements" is instructive here because these claims are *not* preempted by patent law. Reverse payments involve payments from a patentee to another drug manufacturer, with an agreement by the other manufacturer not to produce versions of the patented drug. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 140-41 (2013). The Supreme Court held that such payments could violate antitrust law by diminishing competition and that the claims should be permitted to proceed, reversing the Eleventh Circuit which had found otherwise. *Id.* at 141. Likewise here, the rebates

and other payments made by Manufacturers to PBMs for favorable or exclusive formulary position are payments to diminish competition between the GLP-1s. While the State does not assert antitrust claims, the Supreme Court precedent on such payments further supports the clear conclusion that this type of conduct, which occurs outside the patent system and in the marketplace, is not immunized by patent law.

The rule that marketplace misconduct claims are not preempted logically follows from the fact that "state unfair competition law regulates conduct in a different field from federal patent law." *Hunter Douglas*, 153 F.3d at 1334. The Manufacturers do not address this body of cases, including those already cited by the State, except to recognize that they each involved alleged misconduct in the marketplace, and to wrongly suggest that the State's claims do not. (MDL Dkt. 200-1 at 12-13). Implicit in their argument is the understanding that misconduct in the marketplace is not preempted – a point that is beyond genuine dispute.

C. The Cases Cited By the Manufacturers Are Inapposite, Because They Did Not Involve Marketplace Misconduct

The Manufacturers primarily rely on two cases to argue for preemption, against the weight of the above precedent. Both cases are inapposite, however, because neither involved allegations of misconduct in the marketplace.

Biotech was a pre-enforcement challenge to a statute passed by the District of Columbia's city council. 496 F.3d at 1365. The statute prohibited excessive prices

strictly for patented drugs sold within D.C.[12] *Id.* About two months before the statute was to take effect, two industry groups of drug manufacturers filed suit to challenge the law, alleging it was invalid under the Commerce Clause and preempted by patent law. *Id.* at 1366. The plaintiffs' challenge was to the law on its face – and therefore involved no allegations of unlawful conduct.

As the *Biotech* court said:

> Of course, the patent laws are not intended merely to shift wealth from the public to inventors. Their purpose is to "promote the Progress of ... useful Arts," U.S. Const. art. I, § 8, cl. 8, ultimately providing the public with the benefit of lower price through unfettered competition… If the market functions properly, this new participation will bring down the formerly elevated price of the patented product to competitive levels.

Id. at 1373. The State's claim here is that the Manufacturers, together and in conjunction with the PBM Defendants, have unlawfully manipulated the market, such that the market does not function properly. Quite the opposite of standing as an obstacle to the goals of patent law, the State of Mississippi's claims are in harmony with the federal objective.

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[12] The D.C. statute applied only to patented drugs. *Biotech*, 496 F.3d at 1365. A concurrence to a denial of rehearing noted that "[w]hether future efforts of states to regulate drug prices, which for example did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right, would also be preempted is a question that remains for another day." *Biotechnology Indus. Org. v. D.C.*, 505 F.3d 1343, 1348 (Fed. Cir. 2007) ("*Biotech II*") (Gajarsa, J., concurring).

This further distinguishes the State's case. In addition to involving marketplace misconduct, the state law tort here, like the one at issue in *Dow*, "covers all types of commercial actors and does not single out patent-holders for either increased deference or additional scrutiny." *Dow*, 139 F.3d at 1478.

The Manufacturers' other cited case, *SEPTA*, 102 F. Supp. 3d 688, fares no better. The claims in *SEPTA* were based on the drug manufacturer's use of its patent to set high prices of a single patented drug, as the *SEPTA* complaint made clear from the outset:

> This case involves a drug manufacturer's attempt to exploit the patent laws by selectively charging exorbitant prices for its life-saving Hepatitis-C drug, Sovaldi® (sofosbuvir tablets) ("Sovaldi"). As explained herein, Defendant Gilead Sciences, Inc.'s ("Gilead" or "Defendant") limited rights as a patent holder do not translate into a license to price gouge consumers, state and federal health and welfare programs, and other third party payers under the extraordinary circumstances presented here.

SEPTA Compl., E.D. Pa. Case No. 2:14-cv-06978, Dkt. 1 at ¶ 1. The court saw no allegations of unlawful conduct or wrongdoing, other than the high prices. *SEPTA*, 102 F. Supp. 3d at 704 ("Plaintiffs allege no mistake or other circumstance requiring restitution. They merely allege that they wish they did not have to—or will not in the future have to—pay Gilead the prices it charges for Sovaldi and Harvoni."). The *SEPTA* court was clear in its opinion that the preemptive effect only applied "[t]o the extent that plaintiffs seek to use state law to challenge Gilead's exercise of its exclusive patent rights to make pricing decisions[.]" *Id.* at 703. This is consistent with the rule that preemption does not apply to allegations that include unlawful conduct, unrelated to patent law, rather than mere pricing decisions.

It appears that the application of *Biotech* and *SEPTA* is quite limited. The State has found no reported cases other than *SEPTA* that rely on *Biotech* for its patent

preemption analysis;[13] nor any cases citing *SEPTA* regarding patent preemption. In contrast, *Dow* and *Hunter Douglas*, the State's cited Federal Circuit cases, have been cited extensively on this issue and, like the State's claims, involved allegations of unlawful conduct that is not protected by patent law.

For all these reasons – because the Manufacturers have not met their burden to show the relevance of their alleged patents; because the case law dictates that marketplace misconduct claims like the State's are not preempted by federal patent law regardless; and because the presumptions guiding preemption analysis weigh against preemption – the Manufacturers' asserted preemption fails, and their motion should be denied.

IV. If the Court Grants Manufacturers' Motion, It Should Grant the State Leave to Amend Its Complaint

Even if a court grants a 12(c) motion, the nonmoving party must generally have an opportunity to amend the complaint. *See Klitschko v. Int'l Boxing Fed'n, Inc.*, 2005 WL 8174968, at *4 (D.N.J. Dec. 7, 2005) ("dismissal without leave to amend is justified only on the grounds of bad faith, undue delay, prejudice, or futility."). Should the Court grant Manufacturers' motion, the State requests leave to amend its complaint.

[13] One case, *Grand Gen. Accessories Mfg. v. United Pac.Indus. Inc.*, cited *Biotech* simply for the background propositions that the objectives of patent law determine whether a state law is preempted, and that patents are designed to promote invention by providing the right to exclude others, but not for the analysis relied on by Manufacturers. 2009 WL 10672038, at *7 (C.D. Cal. Jun. 11, 2009).

CONCLUSION

For the foregoing reasons, the Court should deny the Manufacturers' motion for judgment on the pleadings.

Dated: July 23, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on July 23, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notice to all counsel of record.

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